Section 5
510(k) Summary

FEB 18 2014

NAME OF SPONSOR:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) CONTACT:	Mike Ensign Director of Regulatory Affairs and Quality Assurance Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: mensign@odev.com
DATE PREPARED:	October 30, 2013
PROPRIETARY NAME:	KASM® Knee Articulating Spacer Molds
COMMON NAME:	Total Knee Replacement Prosthesis
CLASSIFICATION:	21 CFR 888.3560, Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
DEVICE PRODUCT CODES:	JWH, MBB
PREDICATE DEVICES:	StageOne™ Knee Cement Spacer Molds, *Biomet* (K050210)

Device Description

KASM® knee articulating spacer molds include two single-use molds: one tibial and one femoral. Both molds are comprised of a translucent, firm but flexible USP class VI medical-grade thermoplastic urethane. Multiple sizes are offered for both the femoral and tibial KASM® molds, in order to accommodate a wide range of patient anatomies. The femoral and tibial molds are to be used in the first stage of a two-stage revision knee arthroplasty. The KASM® knee articulating spacer molds are designed to facilitate a surgeon to intraoperatively fashion a polymethylmethacrylate (PMMA) articulating cement spacer (both femoral and tibial components) which contains gentamicin that will serve as a temporary knee prosthesis for an implantation period not to exceed 180 days. The KASM® cement spacers are for cemented use only.

Indications for Use

KASM® is intended for use in temporary total knee arthroplasty procedures with the following indications:

1. Active sepsis which requires a two-stage revision arthroplasty procedure
2. Skeletally mature patients who will consistently use limited mobility assistive devices such as a walker, canes, crutches, etc., for the entire implantation period
3. Implantation period of 180 days or less

Use only with polymethylmethacrylate/gentamicin bone cement.

The articulating cement spacer prosthesis fashioned using the KASM® mold is intended for cemented fixation only.

Technological Characteristics

Feature	Equivalent Device
Articulating Knee Spacer Mold used for fashioning a Polymethylmethacrylate /gentamicin temporary knee prosthesis	StageOne™ Knee Cement Spacer Molds, *Biomet*

There are two differences between the KASM® cement spacer molds and its predicate, the StageOne™ Knee Cement Spacer Molds. First, KASM® molds are fabricated using Pellethane, a medical-grade thermoplastic urethane; StageOne™ Knee Cement Spacer Molds are fabricated from a medical-grade silicone elastomer. Second, the KASM® femoral mold is designed as an open-faced mold to be filled and placed in situ allowing the cement spacer to cure in place in a single step; the StageOne™ femoral mold is designed as a fully enclosed mold that must be filled utilizing a pressurized cement injector system. Once cured, the StageOne™ femoral cement spacer mold is torn open and the released femoral cement spacer is affixed to patient anatomy using a second bone cement curing step.

The KASM® and StageOne™ tibial spacer molds are used in an identical fashion; both molds are open-faced and intended to be filled to the desired thickness, allowed to cure, then affixed to patient anatomy using a second bone cement curing step.

Performance Data

The following non-clinical testing was performed to determined substantial equivalence to the predicate devices:

Property	Result
Gentamicin Elution Rate Study	Substantially equivalent antibiotic elution rate as compared to cement manufacturer's reported elution rate
Tibial Mechanical Strength ****test adapted from ASTM F1800***	Substantially equivalent to StageOne™ tibial cement spacer
Tibial Fatigue Strength ****test adapted from ASTM F1800***	Substantially equivalent to StageOne™ tibial cement spacer
Cement Spacer Wear Study ****test adapted from ISO 14243***	Substantially equivalent to StageOne™

Basis for Substantial Equivalence

This 510(k) demonstrates that the KASM® femoral and tibial cement spacer molds are substantially equivalent to the previously cleared predicate device based on similarities in intended use, design, materials, and mechanical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 18, 2014

Ortho Development Corporation
Mr. Mike Ensign
Director of Regulatory Affairs and Quality Assurance
12187 South Business Park Drive
Draper, Utah 84020

Re: K133449
Trade/Device Name: KASM® Knee Articulating Spacer Molds
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: II
Product Code: JWH, MBB
Dated: January 3, 2014
Received: January 7, 2014

Dear Mr. Ensign:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133449

Device Name
KASM® Knee Articulating Spacer Molds

Indications for Use *(Describe)*

KASM® is intended for use in temporary total knee arthroplasty procedures with the following indications:

1. Active sepsis which requires a two-stage revision arthroplasty procedure
2. Skeletally mature patients who will consistently use limited mobility assistive devices such as a walker, canes, crutches, etc., for the entire implantation period
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133449